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OFFICE OF PETITIONS

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111

In re Patent No. 7,537,900

Dotan, et al. : DECISION ON Application No. 10/634,309 : REQUEST FOR

Issue Date: May 26, 2009 : RECONSIDERATION OF

Filed: August 4, 2003 : PATENT TERM ADJUSTMENT Attorney Docket No. : AND NOTICE OF INTENT TO

25681-501 : ISSUE CERTIFICATE OF

: CORRECTION

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d), filed July 24, 2009. Patentees request that the determination of patent term adjustment be corrected from four hundred thirty-six (436) days to nine-hundred ninety-one (991) days.

The request for reconsideration of the patent term adjustment indicated in the patent is <a href="GRANTED">GRANTED</a> to the extent indicated herein.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond. No extensions of time will be granted under 37 CFR 1.136.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of four hundred forty-seven (447) days.

#### BACKGROUND

This application was filed on August 4, 2003. On May 26, 2009, the application matured into U.S. Patent No. 7,537,900 with a revised patent term adjustment of 436 days. The Office determined that the 636 days of Office delay pursuant to 35

U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b)<sup>1,2</sup> overlaps with the 721 days of Office delay pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1) and (a)(2)<sup>3,4</sup> accorded prior to the issuance of the patent. As such, the Office allowed only entry of the adjustment of 721 days for Office delay. No additional days of patent term adjustment were entered at issuance under the three-year pendency provision. The patent issued with a revised patent term adjustment of 436 days (721 days of Office delay - 285 days of applicant delay.)

Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b)[.]

- (a) Failure to take certain actions within specified time frames. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:
- (1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;
- (2) Respond to reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was filed or appeal was taken;

<sup>&</sup>lt;sup>1</sup> Pursuant to 35 U.S.C. 154(b)(1)(B), 37 CFR 1.702(b) provides, in pertinent part, that:

 $<sup>^2</sup>$  As of the filing of the RCE on May 1, 2008, the application was pending three years and 636 days.

<sup>&</sup>lt;sup>3</sup> 37 CFR § 1.702, provides grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

<sup>&</sup>lt;sup>4</sup> A first Office action was not mailed until April 10, 2006, fourteen months and 553 days after the application filing date of August 4, 2003. A final rejection was mailed November 1, 2007, four months and 168 days after a reply was filed on January 17, 2007.

On July 24, 2009, patentees timely submitted this request for reconsideration of patent term adjustment asserting that the correct number of days of Patent Term Adjustment is 991 days, based in part, under the courts interpretation of the overlap provision as set forth in <a href="Wyeth v. Dudas">Wyeth v. Dudas</a>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees asserts that pursuant to <a href="Wyeth">Wyeth</a>, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentee maintains that the total non-overlapping PTO delay under § 154(b)(1)(A) & (B) is 1,188 (721 + 467) days as these periods do not occur on the same day.

Patentees further asserts that the period reduction of 111 days under 37 CFR 1.704(c)(10) for filing an amendment under § 1.312 and drawings on February 5, 2009, after the mailing of the notice of allowance, is incorrect. Rather, the period adjustment set forth in § 1.703 should be reduced by only 23 days.

#### OPINION

Patentees dispute the reduction of 111 days for filing the amendment under § 1.312 and drawings on February 5, 2009, after the mailing of the notice of allowance pursuant to 37 CFR 1.704(c)(10). Specifically, patentees assert that the Office mailed a "Response to Rule 312 Communication" in response to the amendment and drawings on February 27, 2009. Patentees contend that the period of reduction should be 23 days (not 111 days), counting the number of days beginning on the filing date of the amendment under § 1.312 and drawings, February 5, 2009, and ending of the mailing date of the "Response to Rule 312 Communication", February 27, 2009, in response to the amendment under § 1.312 and drawings.

Patentees' contention is well taken. 37 CFR 1.704(c)(10) provides that:

Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper;

or

#### (ii) Four months;

In this instance, the record reveals that the Office took action in response to the filing of amendment under § 1.312 and drawings on February 27, 2008. Accordingly, the period of adjustment of the term of the patent should have been reduced by 23 days, not 111 days. The period of reduction of 111 days will be removed and a period of reduction of 23 days will be entered.

However, a further review of the application history reveals that patentees should have been assessed an additional period of delay for the filing of a "COMMUNICATION" on March 11, 2009, after the mailing of the notice of allowance, which under the circumstances of this application, is a ground for reduction of patent term adjustment under 37 CFR 1.704(c)(10).

In this instance, it is undisputed that patentee filed the "COMMUNICATION" after the mailing of the notice of allowance. The Office did not address the "COMMUNICATION" before the issuance of the patent. Thus, the period of adjustment should have been reduced by the lesser period of 77 days, beginning on the date the "COMMUNICATION" was filed, March 11, 2009, and ending on the date the patent issued, May 26, 2009. Accordingly, a period of reduction of 77 days will be entered.

With regard to the argument under 37 CFR 1.702(b), patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A).

Patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR  $1.703(f)^5$  and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154 (b) (1) (B), 35 U.S.C. 154 (b) (2) (A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of

<sup>5</sup> Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the application filing date under 35 U.S.C. 111(a), August 4, 2003, and ending on the date of filing of a request for continued examination (RCE), May 1, 2008, (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). The relevant period ends with the filing of the RCE as the three-year time frame specified in 35 U.S.C. 154(b)(1)(B) does not include the period subsequent to the filing of the RCE. 35 U.S.C. 154(b)(1)(B)(i).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1) and (a)(2), 721 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the filing of the request for continued examination. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), 636 days of patent term adjustment accrued for Office issuance of the patent more than 3 years after the filing date of the application<sup>6</sup>.

<sup>&</sup>lt;sup>6</sup> The Office notes that patentees incorrectly calculated the period of adjustment under 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b) ("Three Years Delay"). Furthermore, patentees used the incorrect Three Years Delay period in calculating the requested patent term determination. Pursuant to 37 CFR 1.703(b), the period of adjustment is 636 days (not 635 days as suggested by patentees), counting the number of days in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a), August 5, 2006, and ending on the date the request for continued examination was filed, May 1, 2008. "When a period is

All of the 636 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 721 days of patent term adjustment under 37 CFR 1.702(a)(1) and (a)(2). Entry of both the 721 days and the 636 days is neither permitted nor warranted. 721 days is the actual number of days issuance of the patent was delayed.

#### CONCLUSION

In view of, the patent term adjustment indicated on the patent should be 447 days (721 days of Office delay - 274 (84 + 90 + 23 + 77) days of applicant delay)).

This matter is being referred to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by 447 days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

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Enclosure: Copy of DRAFT Certificate of Correction

indicated (in 37 CFR 1.703 or 1.704) as 'beginning' on a particular day, that day is included in the period, in that such day is 'day one' of the period and not 'day zero.'" MPEP 2731. "For example, a period beginning on April 1 and ending on April 10 is ten (and not nine) days in length." Id.

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# UNITED STATES PATENT AND TRADEMARK OFFICE

## **CERTIFICATE OF CORRECTION**

**PATENT** 

: 7,537,900 B2

DATED

: May 26, 2009

INVENTOR(S): Dotan, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

Subject to any disclaimer, the term of this patent is extended or adjusted [\*] Notice: under 35 USC 154(b) by (436) days

Delete the phrase "by 436 days" and insert – by 447 days--